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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/609,137

06/26/2003

Soheil Shams

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7590

04/03/2008

SOHEIL SHAMS, PHD  
2121 ROSECRANS AVE.  
SUITE 3315  
EL SEGUNDO, CA 90245

EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/609,137	<b>Applicant(s)</b> SHAMS, SOHEIL	
	<b>Examiner</b> John S. Brusca	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-20,22-39 and 41-81 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,24,25,43,44,60,68 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-20,22,23,26-39,41,42,45-59,61-67,69-75 and 77-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 3-20, 22-39, 41-81 are pending.

Claims 5, 6, 24, 25, 43, 44, 60, 68, and 76 are withdrawn

Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 42, 45-59, 61-67, 69-75, and 77-81 are rejected.

### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 March 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 1-4, 7-23, 26-42, 45-59, 61-67, 69-75, and 77-81 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement in the Office action mailed 18 September 2007 is withdrawn in view of the amendment filed 14 March 2008.

### ***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 42, 45-59, 61-67, 69-75, and 77-81 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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Claims 1, 3, 4, 7-19, and 58, 59, and 61-65 are drawn to a process and claims 20, 22, 23, 26-39, 41, 42, 45-57, 66, 67, 69-75, and 77-81 are drawn to an apparatus and computer programs for executing the process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (*State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998), *AT&T Corp. v. Excel Communications Inc.* (CAFC 50 USPQ2d 1447 (1999))). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. *See In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful" the claim must produce a result that is specific and substantial. For a claim to be "concrete" the

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process must have a result that is reproducible. For a claim to be “tangible” the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 1, 3, 4, 7-20, 22, 23, 26-39, 41, 42, 45-59, 61-67, 69-75, and 77-81 do not require production of a tangible result in a form that is useful to the user of the process or apparatus. A tangible result requires that the claim must set forth a practical application to produce a real-world result. The claims determine spatial expression patterns of genes, but do not produce a result of a spatial expression pattern that is interpretable by a user. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claims 20, 22, 23, 26-39, 41, 42, 45-57, 66, 67, 69-75, and 77-81 are drawn to a computer program on computer readable media. A review of the specification does not show a definition of computer readable media such that excludes an embodiment that is information on a carrier wave. As such an embodiment of the claims read on non-statutory subject matter.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1, 3, 4, 9-17, 58, 59, and 62-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Caron et al.

The claims are drawn to a method of aligning gene expression data of exons to a chromosomal map thereby creating an expression map. In some embodiments sets of coexpressed genes are identified, a plurality of expression data from different conditions are mapped to chromosomal positions, and an entire chromosome is mapped.

Caron et al. details results from a complete human transcriptome map. Caron et al. shows that SAGE expression data was used on page 1289 (which is derived from processed cDNA transcripts, known in the art to consist of exons, as shown in page 3 of the supplemental material). Caron et al. shows a portion of the complete transcriptome map in figure 1 which shows an expression map of human chromosome 11 in which the expression profiles of eight different cell types are indicated. Caron et al. notes the presence of regions of increased gene expression (termed RIDGES) on page 1290-1292.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 18-20, 22, 23, 28-39, 41, 42, 47-57, 66, 67, 70-75, and 78-81 rejected under 35 U.S.C. 103(a) as being unpatentable over Caron et al. in view of Kanehisa et al.

The claims are drawn to a method of aligning gene expression data of exons to a chromosomal map thereby creating an expression map. In some embodiments sets of

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coexpressed genes are identified, a plurality of expression data from different conditions are mapped to chromosomal positions, and an entire chromosome is mapped. In some embodiments the claims are drawn to computers and programs that execute the method. In some embodiments the maps are of different genomes.

Caron et al. details results from a complete human transcriptome map. Caron et al. shows that SAGE expression data was used on page 1289 (which is derived from processed cDNA transcripts, known in the art to consist of exons, as shown in page 3 of the supplemental material). Caron et al. shows a portion of the complete transcriptome map in figure 1 which shows an expression map of human chromosome 11 in which the expression profiles of eight different cell types are indicated. Caron et al. notes the presence of regions of increased gene expression (termed RIDGES) on page 1290-1292. Caron details use of databases and algorithms to generate and analyze the data of their method of making a transcriptome map throughout the supplemental material pages 1-11.

Caron et al. does not explicitly show computers and programs that execute their method. Caron et al. does not show comparison of expression profiles of different genomes.

Kanehisa et al. describe a knowledge base termed KEGG in the abstract and throughout that comprises genomic information including genomic maps and gene expression profiles. Kanehisa et al. states on page 27 that their knowledge base uses computerized tools and software to facilitate the analysis depicted in figure 1. Kanehisa et al. shows on page 28 that their system comprises gene expression profiles that allow the user to detect co-regulated genes that are clustered on a chromosome. Table 1 shows that KEGG has 23 complete genome maps and four

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sets of expression maps. Kanehisa et al. shows comparison of orthologs and genome-genome comparisons on page 29.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of generating expression map comparisons of Caron et al. by use data of multiple genomes because Kanehisa et al. shows databases and methods of comparing data of multiple genomes to compare orthologs. It would have been further obvious to automate the procedures of Caron et al. because Caron et al. discusses use of programs and computer databases, Kanehisa et al. shows that similar collections of expression maps can be analyzed by computers and programs, and because automation of a manual activity is recognized as obvious, as noted in the MPEP at section 2144.04:

### III. AUTOMATING A MANUAL ACTIVITY

In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined “old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed.” The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).

#### *Allowable Subject Matter*

10. Claims 7, 8, 26, 27, 45, 46, 61, 69, and 77 are not anticipated or obvious over the prior art.



***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/  
Primary Examiner  
Art Unit 1631

jsb